Regulation on Approval of Functional Ingredient for Health Functional Food

Enacted by the Commissioner of the Food and Drug Administration Notification No. 2004-12, Jan. 31, 2004
Amended by the Commissioner of the Food and Drug Administration Notification No. 2006-36, Aug. 29, 2006
Amended by the Commissioner of the Food and Drug Administration Notification No. 2007-51, Jul. 11, 2007

Chapter 1. General Provisions

Article 1. (Purpose) The purpose of this Regulation is to provide the appropriate approval work relating to the standards and specifications, safety, functionality and consumption amount, etc. of ingredient by prescribing matters relating to approval criteria, approval procedure, scope and requisites of submitted documents, etc. necessary for the approval of functional ingredient for health functional food (hereinafter referred to as "ingredient") under Articles 14(2) and 15(2) of the 「Health Functional Food Act」 (hereinafter referred to as the "Act")

Article 2. (Definition): (1) For the purpose of this Regulation, the definitions of terms shall be as follows:

1. The term "functional ingredient" means any ingredient with functionality used in manufacturing of health functional food such as raw materials from animal, plant or raw material originated from microorganism; its extracts and purified substances; vitamins and minerals; or their synthetics or composites, etc.;
2. The term "functional component" means a component responsible for the functionality in ingredient;
3. The term "marker compound" means a component determined for the purpose of quality control among those chemically identified components;
4. The term "raw material" means a original substance used in manufacturing the ingredient;
5. <Deleted> (on July 11, 2007)
6. The term "detrimental substance" means any hazardous material to human body because of the possibility of its contamination or residue from ingredient or remained from manufacturing processes such as microorganism, heavy metal, pesticide residue, solvent residue and others.

(2) The definitions of terms not defined in this Regulation shall follow the Act or the Official Book of Health Functional Food.

Article3 (Review subject scope) The scope of review subject under this Regulation shall be as follows:

1. Ingredient not notified, or modification or addition of the content in accordance with Articles 14(1) and 15(1) of the Act (excluding specially intended food); or
2. Modification or addition of contents recognised in accordance with Articles 14(2) and 15(2) of the Act

Article 4. (Approval criteria) The approval criteria of ingredient shall be as follows:

1. It shall be complied with the Health Functional Food Act; and
2. Safety and functionality shall be ensured and scientifically proved.

Chapter 2. Approval procedure

Article 5 (Approval application) Any person who intends to obtain an approval for the ingredient among business persons under Article 5(1) or 6(1) of the Act shall submit health functional food approval application (including electronic application form), annexed the Form 1, along with the following documents(including electronic documents) to the Commissioner of the Food and Drug Administration:

1. Two copies of documents (including an original copy) under Article 12(1);
2. A CD containing the submitting documents; and
3. Product or test product and the standard of function component (or marker compound)
   In case of an import item which has never been distributed as food or food additive domestically, the item shall be used for research and investigation under annexed the Table 2 No. 1 (a)(2) related to Article 8 of the Act and Article 10 of the Enforcement Rule
4. Written result of examination issued by a domestic health functional food examination laboratory.

Article 6 (Treatment period) (1) The treatment period necessary for the approval of ingredient shall be within 120 days from the date of receiving.

(2) In case where there is the supplementary request on the documents under Article 7, the Commissioner of the Food and Drug Administration shall decided the supplementary period under the Civil Petitions Treatment Act.

Article 7 (Supplementary documents etc.) (1) The Commissioner of the Food and Drug Administration shall express the necessary matters in detail and request supplement of documents to the applicant if the submitted documents fall under any of the followings:

1. If type, scope, contents, requisites, etc. of submitted documents are not complied with the provisions of Articles 12 and 13; or
2. Additional documents etc. are especially required for appropriate evaluation.

(2) The Commissioner of the Food and Drug Administration may hear the opinion on the data submitted by the applicant in case where verification of fact is necessary because the item is not suitable for the provision of paragraph (1).

Article 8 (Return of application documents) The Commissioner of the Food and Drug Administration shall return the application documents to the applicant with the expressed reasons, if application falls under any of the followings:

1. In case where the ingredient is not complied with Article 4; and
2. In case where the applicant dose not submit relevant document within the supplementary period under Article 6 (2).

Article 9 (Approval and deliberation) The Commissioner of the Food and Drug Administration shall review the submitted documents by the applicant according to the provisions of Articles 14 through 16, and recognize as ingredient if it is suitable as a result of the deliberation of the Health Functional Food Deliberation Committee under the Article 27 of the Act.

Article 10 (Notification of approval etc.) The Commissioner of the Food and Drug Administration shall issue the "Certificate of Functional Ingredient for Health Functional Food," annexed the Form 2, to the applicant when recognizing the ingredient.

Article 11 (Modification of approval matters, etc) (1) Any person who intends to modify the contents of the certificate under Article 10 shall submit the 'Application of Modification on Certificate of Functional Ingredient for Health Functional Food,' annexed the Form 3, to the Commissioner of the Food and Drug Administration.

(2) When receiving the application of modification under paragraph (1), the Commissioner of the Food and Drug Administration shall determine whether he accepts the modification under the condition without changing ingredient after reviewing the validity of modification reasons.

Chapter 3 Submission documents

Article 12 (Scope of submission documents) (1) The documents submitted by the applicant to be recognized as the ingredient shall be as follows and may be submitted by entering the documents in "the Health Functional Food Approval Application Program" :

1. Executive summary of whole submitted documents;
2. <Deleted> (on August 29, 2006);
3. Origin, developing history, current status of approval and use in domestic or foreign countries etc.;
4. Manufacturing methods and related data;
5. Characteristics of the ingredients;
6. Specification on functional component (or marker compound) and data on test method;
7. Specification of detrimental substance and related data for test method;
8. Safety;
9. Functionality contents and related data ;
10. Consumption amount, consumption method, warning notice for consumption and related data for such establishment;
11. <Deleted> (on July 11, 2007)
12. Confirmation data that ingredients are not identical with or similar to medicine.

(2) The preparation method for submitted documents shall be as follows:

1. Submitted documents shall be complied with the requisites under Article 13 and marked with the table of contents, index number and number by document according to the listed sequence by each of section. Provided, That if the submitted documents are exempted or omitted

according to the provisions of each Article, or are unable to be prepared, the reasons shall be described in detail and attached in the relevant section;

2. The executive summary shall be attached to understand the overview of whole documents, and index number by document shall be given to the end of the each content in order to figure out the links between the contents in the executive summary and each specific document;
3. Where there are excessive documents depending on sections, the brief section summary shall be attached to the starting page of document in relevant sections to facilitate understanding;
4. Both original copy and executive summary shall be submitted and Korean translation documents shall be submitted in case of documents written in foreign language other than English; and
5. The applicant shall acquire the confidence of submitted documents.

Article 13 (Contents and requisites of submitted documents) The contents and requisites of submitted documents under Article 12 shall be as follows:

1. Executive summary of whole submitted documents (Brief summary for contents of subparagraphs 3 through 12);
2. <Deleted> (on August 29, 2006);
3. Origin, developing history, current status of approval and use in domestic or foreign countries etc.;
   (a) Origin and developing history
   It shall be listed when, in which country, and how ingredients are developed. Especially in case that natural products is used as the raw material, the origin, the scientific name, the place of origin and the part used, etc. shall be listed in detail.
   (b) Current status of recognition and permission in domestic or foreign countries
   The contents related to the status of recognition and permission, and standards and specifications for use etc. in domestic or foreign countries, and international organization shall be listed precisely. If ingredients are under review by the international organization such as Codex Alimentary Commission (CAC), etc., data related to safety evaluation, standard of use and specification, etc. shall be researched and attached to submission.
   (c) Current status of use in domestic or foreign countries
   If ingredients have been used for foods, etc. in domestic or foreign countries, data related to the purpose of use, the amount of distribution, manufacturer, and actual condition of consumption shall be attached to submission.
4. Manufacturing methods and related data;
   Manufacturing methods shall be listed in detail, especially all matters related to evaluation of safety and functionality such as kinds of extraction solvent, enzyme, microorganism, etc. in manufacturing processes. In case of imported health functional foods, documents issued from manufacturer shall be submitted. In addition, in case of mixing more than two raw materials, the content and name of each ingredient shall be listed.

5. Characteristics of the ingredients;
   (a) Data on appearance and property of matter, etc. which may characterize the corresponding

ingredient.

(b) Data on functional component (or marker compound) for the confirmation of standardization of the corresponding raw material and evidence data on functional component (or marker compound)

In such a case the content unit of functional component (or marker compound) shall be established on the basis of results of multiple tests considering the characteristics of ingredient such as the manufacture of ingredient, the production and processing of ingredient, stability, etc. However, if it is unsuitable to establish content, it is allowed to establish through potency test or identity test.

(c) Change in productivity and the content functional component (or marker compound) following production steps.

6. Specification on functional component (or marker compound) and data on test method

(a) The specification of functional component (or marker compound) shall be established by the upper and lower limits in percentage for the value desired to be displayed considering analysis error. Generally, in case of a single component, it is established in terms of the displayed or value or more and in case of an extract, it is established in terms of 80~120% of the displayed value in principle. However, if there is a reasonable reason, it may be established otherwise.

(b) The test method of functional component (or marker compound) shall be suitable for the analysis of specification of functional component (or marker compound). For test method, a method publicly recognized domestically and overseas is recommended such as the health functional food code, the food code, the food additive code, CAC regulation and AOAC method, etc. However, if there is no publicly recognized method or the method presented by the applicant is recognized as more appropriate, the applicant's method may be used. In such a case, the applicant shall prove the suitability of the test method presented, referring to annexed the Table 1.

(c) Written results of examination by a domestic health functional food examination laboratory.

The written results of examination and analysis data by a domestic health functional food examination laboratory shall be submitted so that the suitability of the specification and test method of established functional component (or marker compound) and can be reviewed.

(d) In case where two or more ingredients are mixed, the specification and test method of functional component (or marker compound) of each component shall be established.

(e) ~ (g) <Deleted> (on July 11, 2007)

7. Specification of detrimental substance and related data for test method;

(a) The specification and test method for necessary items shall be established referring to annexed the Table 2, in order to secure safety from detrimental substance with possible contamination or residue from raw materials and manufacturing processes.

(b) For the test method of detrimental substance, a method publicly recognized domestically and overseas is recommended such as the health functional food code, the food code, the food

additive code, CAC regulation and AOAC method, etc. However, if there is no publicly recognized method or the method presented by the applicant is recognized as more appropriate, the applicant's method may be used. In such a case, the applicant shall prove the suitability of the test method presented, referring to annexed the Table 1.

(c) Written results of examination by a domestic health functional food examination laboratory.
The written results of examination and analysis data by a domestic health functional food examination laboratory shall be submitted so that the suitability of the specification and test method of established detrimental substance and can be reviewed.

8. Safety;

(a) Scientific data verifying that ingredient is not harmful to human body when taken as presented shall be submitted.

(b) Referring to annexed the Table 2, the evidence data of consumption, safety information on functional component or related components, evaluation of consumption amount, nutritional evaluation, bioavailability, human study data (interventional study, epidemiological study, etc.), and toxicological data may be used for safety data.

(c) Safety documents shall fall under one of the followings:

a. The evidence data of consumption shall be the historic record of use to verify the safety of such ingredient and the scientific data that describe manufacturing methods, usage, consumption amount, etc.

b. Safety documents on functional component or related substances shall be articles published or issued publication certificate in domestic or foreign academic journals, domestic or foreign government reports, or reports by international organization, related database search results, etc.

c. Documents on evaluation of consumption amount shall be prepared with various scientific data (survey data on actual condition of consumption, statistical data, etc.).

d. Documents on nutritional evaluation, bioavailability, human study, etc. shall be articles published or issued publication certificate in domestic or foreign academic journals. Provided, That if the report under Article 9(C)(1) may be used for human study.

e. Toxicological data shall be one of the following subparagraphs:

1) The report may be used if it is conducted by the institution operated under the Good Laboratory Practice (GLP) in accordance with OECD Test Guideline provided by Organization for Economic Cooperation and Development (OECD) or the equivalent test guidelines.

2) <Deleted> (on July 11, 2007)

9. Functionality contents and related data;

(a) Functionality contents

Useful effect on health purposes from consumption of such ingredient shall be listed.

(b) Human study, animal study, *in vitro* study, review, meta-analysis, evidence data oftraditional use, etc. may be used as functionality data.

a. Data on human study such as intervention or observation study, etc. shall be submitted to confirm the functionality of such ingredient on human body.

b. Documents on animal study, *in vitro* study, review, meta-analysis, evidence oftraditional use, etc. shall be submitted for scientific support on human study results.

c. In case of mixing two or more raw materials, the functionality of mixed ingredient shall be proved, and the valid reason for mixing and scientific evidence shall be submitted.

(c) Documents on functionality shall fall under one of the followings:

a. Functionality data shall be articles published or issued publication certificate in domestic or foreign academic journals, domestic or foreign government reports, or reports by international organization. Provided, in case of human study, the report may be used if it is conducted by domestic or foreign specialized institutions, such as hospital, university, or research institute, etc. under the Guideline for Good Clinical Practice by the International Conference on Harmonization (ICH GCP) or equivalent guidelines to protect the human right of subjects as well as guarantee the creditability of experimental results. Provided, That if it is submitted as report, protocol and final report approved by the Institutional Review Board (IRB) shall be submitted.

b. The evidence data of consumption shall be the historic record of use to verify the safety of such ingredient and the scientific data that describe manufacturing methods, usage, consumption amount, etc.

10. Consumption amount, consumption method, warning notice for consumption and related data for such establishment;

(a) Minimum and maximum daily intake that can show functionality shall be established to ensure the safety of ingredient based on the safety and functionality data. Provided, That if it is difficult to establish the minimum and maximum daily intake, the appropriate range of consumption amount may be established.

(b) Based on functionality data, consumption method shall be listed to achieve the most effectiveness of functionality of such ingredient.

(c) The warning notice for consumption shall be listed by considering the excessive consumption of such ingredient, interaction with foods or medicinal components, susceptible population (pregnant and lactating women, children, the elderly, etc.), etc.

11. <Deleted> (on July 11, 2007)

12. Confirmation that ingredient is identical with or similar to medicine.

It shall be confirmed that ingredient is not identical or similar to the medicine according to Regulation on Prohibited Ingredients, etc. for Health Functional Food (Food and Drug Administration Notification).

Chapter 4 Principle of evaluation

Article 14 (Standards and specifications) (1) The commissioner of Food and Drug Administration shall evaluate whether the origin, the scientific name, the place of origin, and part used, etc. of ingredient applied are described in detail, and in case of compound ingredient, whether the

contents of each raw material are described well.

(2) The Commissioner of the Food and Drug Administration shall evaluate whether solvent, enzyme, etc. used in the manufacturing processes of the applied ingredient are used appropriately according to the health function food code, the food code and the food additive code.

(3) The Commissioner of the Food and Drug Administration shall evaluate whether the content, specification and test method of functional component (or marker compound) of ingredient are suitably established and the results of test by the domestic health function food examination laboratory is appropriate. He shall also evaluate whether change in contents of functional component (or marker compound) by manufacturing steps are properly analyzed from raw materials through the ingredient applied.

(4) The Commissioner of the Food and Drug Administration shall evaluate whether the specification of detrimental substance in ingredient is established so that safety can be secured and shall evaluate whether the results of test by the domestic health function food examination laboratory is appropriate.

(5) <Deleted> (on July 11, 2007)

Article 15 (Safety) The Commissioner of Food and Drug Administration shall evaluate whether it ensures safety of such ingredient by reviewing overall data submitted on origin, development history, current status of approval and use in domestic or foreign countries, manufacturing methods, characteristics of ingredient, traditional use, consumption amount evaluation, nutritional evaluation, bioavailability, results of human study, results of toxicological test, etc.

Article 16 (Functionality) (1) To confirm the functionality of such ingredient, the Commissioner of Food and Drug Administration shall individually evaluate the submitted functionality documents according to research type and quality and totally evaluate the quantity, consistency and applicability of research.

(2) Functionality shall be recognized under paragraph (1) as follows:

1. If the functionality data show the reduction of disease risk occurrence and the level of scientific evidence data is high enough to reach scientific agreement, 'reduction of disease risk' shall be recognized; and
2. From the submitted functionality data, if it has the specific effects on normal function of human body or biological activity so that shows health contribution or function enhancement, or health maintenance or improvement, 'other function' shall be recognized.

ADDENDA

(1) (Enforcement date) This Notification shall enter into force on the date of its announcement.

(2) (Transitional measures related to ingredient in the middle of examination of approval) In case where the approval application was submitted before this Notification enters into force and the examination of approval is in progress, the previous Notification shall be applied.

(3) (Period of validity) The provisions of Article 13(8)C(5)(2) will be valid until Dec. 31, 2006.

ADDENDA (Jul. 11, 2007)

(1) (Enforcement date) This Notification shall enter into force on the date of its announcement.

(2) (Transitional measures related to ingredient in the middle of examination of approval) In case where the approval application was submitted before this Notification enters into force and the examination of approval is in progress, the previous Notification shall be applied.

(3) (Transitional measure on functional ingredient which is not approved of standards and specifications) Functional ingredient which is approved of safety and functionality according to "Regulation on Approval of Health Functional Food Functional Approval" (Food and Drug Administration Notification No. 2004-12, enacted on January 31, 2004) but whose standards and specifications are not established may apply for criteria and specifications under this Notification.

[Annexed the Table 1]

Definition and Application of Check Items for Test Method Validation

Item	Definition	Application		
		Functional Component		Detrimental Substance (Quanti-tative)
		Quantitative test	Identity test	
Specificity	1. Capability for selectively measuring target analysis substance when it is mixed with impurities, decomposed substances, mixture components, etc.	Yes	Yes	Yes
Accuracy	Degree of agreement between test results and know true values and standard values	Yes	No	Yes
Precision	Degree of distribution among measured values when samples that are obtained from homogeneous material many times are measured in a predetermined condition	Yes	No	Yes
Quantitation Limit	The minimum quantity of target analysis substance among samples that can be expressed with proper accuracy and precision	No	No	Yes
Linearity	Capability for obtaining linear measured values among samples in a predetermined range against the quantity (or concentration) of target analysis material	Yes	No	Yes
Range	Region between the upper and lower limits of target analysis material among samples that can sufficiently present proper precision, accuracy and linearity	Yes	No	No

[Annexed the Table 2]

Items for Establishment of Detrimental Substance Specifications

Category	Item		Specification	Remark
A	Heavy metal	Lead	< 10.8㎍/day*	
		Total arsenic	< 150㎍/day*	
		Cadmium	< 3.0㎍/day*	
		Total mercury	< 2.1㎍/day*	
	Micro-organism	Coli group	Negative	
		Number of germs	≤ 100/g (Liquid product only)	
	Solvent residue	Hexane	< 0.005g/kg	If used
		Isopropyl alcohol	< 0.05g/kg	
		Ethyl acetate	< 0.05g/kg	
		Acetone	**	
		Methyl alcohol	**	
B	Animal medicine	Antibiotic	Following the allowable residue limit of the raw material	
		Synthetic antimicrobial		
		Vermifuge		
		Synthetic hormone		
	Fungal toxin	Aflatoxin		
		Patulin		
		Ochratoxin		
		Other fungal toxin		
	Radioactive contamination	^{131}I	≤ 300Bq/Kg, L	
		$^{134}Cs+^{137}Cs$	≤ 370 Bq/Kg, L	
C	Pesticide residue	Endrin	Following the allowable (residue) limit of the raw material	
		Dieldrin		
		Aldrin		
		BHC		
		DDT		
		Other pesticide		

* Average body weight is assumed to be 60kg. If the subject of consumption has a different average body weight, the standars may be changed considering the average body weight of Korean dietary reference intake.

** If residue remains inevitably in the course of manufacturing, the substance shall be established to be managed at the minimum quantity achievable in the manufacturing processes.

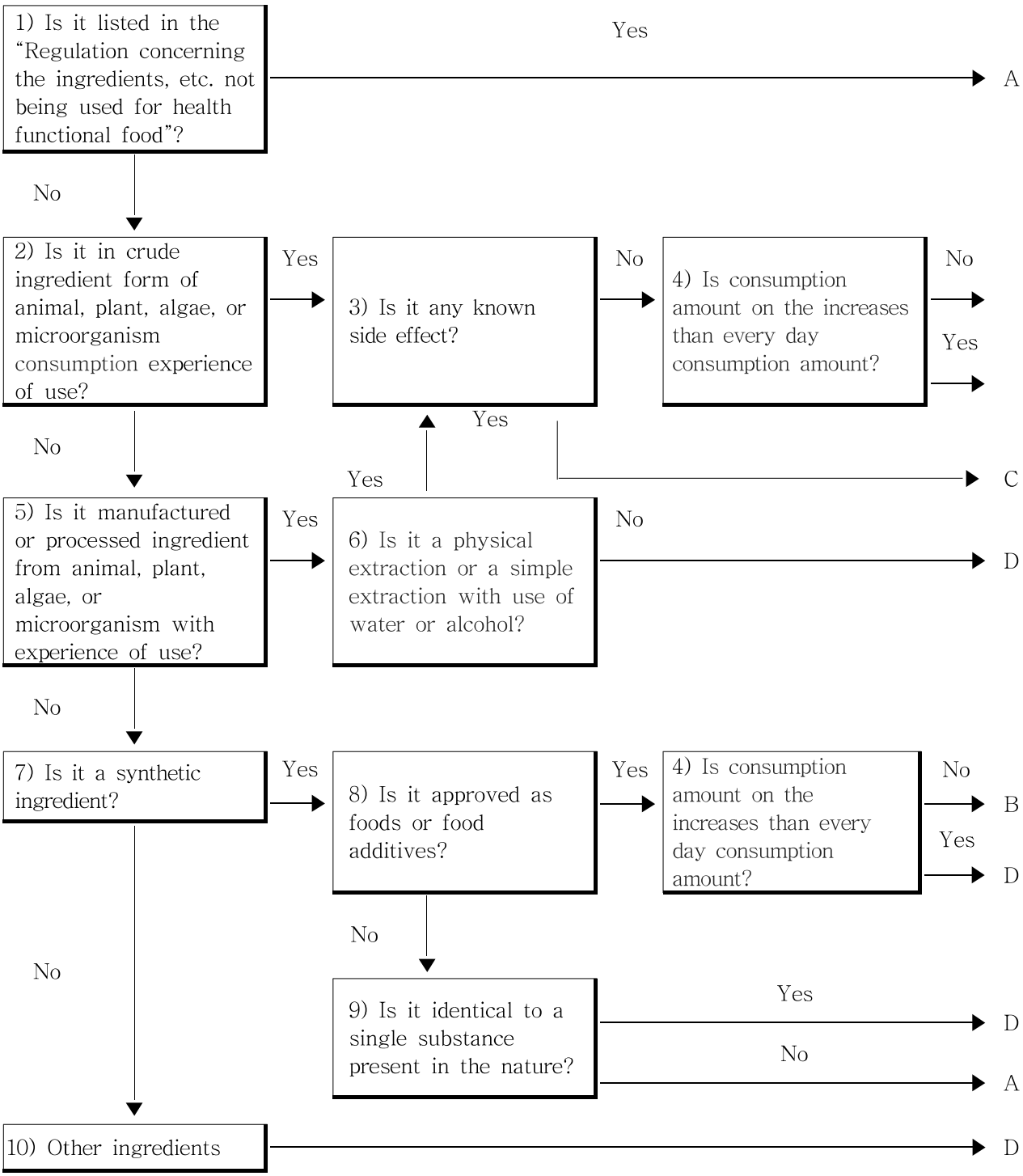
A: Item for which specification shall be established at all time and whose results of examination shall be submitted.

B: Item for which specification shall be established and whose results of examination shall be submitted depending on ingredient.

C: Item whose results of examination shall be submitted, but specification may not be established.

[Annexed the Table 3]

Decision Tree for Safety Evaluation of Functional Ingredient for Health Functional Food (relating to Article 13(8))



<1. Scope of submitted document on safety>

Scope of submitted documents on safety	A	B	C	D
Cannot be applied as health functional food	√			
Evidence of consumption [1)]		√	√	√
Safety data on functional ingredient or related substances [2)]		√	√	√
Documents on evaluation of intake level [3)]		√	√	√
Documents on nutritional evaluation, bioavailability, human study [4)]			√	√
Documents on toxicological study [5)]				√

1) Evidence documents on consumption based on Official book of Health Functional Food, Official book of Food, Official book of Food additives, Scientific documents on historical/traditional use/ documents on recognition from domestic or foreign government institution, etc.

2) Documents on safety/toxicity of functional ingredient or related substances can be collected from databases.

3) Documents on the average intake and recommendation intake analyzed by national nutrition survey or survey on consumption behavior.

4) Documents on the effect of ingredient intake on adsorption, distribution, metabolism, and excretion of other nutrients bioavailability; interventional study, epidemiological study.

5) Toxicity studies shall include the single dose-toxicity (rodents, non-rodents), 3 month repeated dose toxicity (rodents), and genotoxicity (reverse mutation test, chromosomal aberration test, and micronucleus test). Depending on the characteristics of the ingredient or constituent, reproductive toxicity, antigenicity, immunotoxicity, carcinogenicity, or others. Provided the safety can be demonstrated by other safety documents, exemption may be applied.

<2. Significant points needed to be considered in making a decision>

1) Determined if the ingredient is specified at the “Regulation on Prohibited Ingredients, etc. for Health Functional Food.” in the Manufacture of Drug products (KFDA Notification)

2) Determined if the ingredient is derived from historically used animals, plants, microorganism without processing such as extraction or fermentation (e.g. powder of raw materials). Historical use indicates ingredient listed in Official Book of Health Functional Food, Official book of Food, Official book of Food additives, scientific documents on historical/traditional use/ documents on recognition from domestic or foreign government institution, etc.

3) Determine by searching the databases if the ingredient may contain detrimental substances can that cause toxicity or adverse health effects.

4) Determined if the recommended intake is over three times of average daily intake or extreme amount (95 percentile) in care of food ingredient. Determine if recommended intake is over average daily intake in case of medicinal ingredient. Provided lacking in evidence of intake, it shall be judged that intake is changed.

5) Determined if the ingredient or substances is derived from historically used animals, plants, microorganism processing such as extraction, fermentation, separation, decomposition.

6) Determined if the ingredient is obtained from extraction through compression or osmosis, or a simple extraction made of extraction or leaching with water or alcohol followed by separating pellet from supernatant. If manufacturing methods meet one of following subparagraphs, it is applied to this category.

- Ingredient extracted using solvents, other than water and alcohol, approved by “Official Book of Health Functional Food, Chapter 2. Standard and Specification of Health Functional Food”.

- Ingredient from separation of specific component, purified ingredient, or modified

- ingredient after separation.

7) Determine if the ingredient or substances is composed of synthetic chemicals.

8) Determine if the ingredient is recognized as food ingredient or food additive.

9) Determine if the ingredient is not recognized as food ingredient or food additive but identical to natural substance.

10) Applicable to all ingredients except those of 1), 2), 3), 6), and 9).

※ In case of compound ingredients, the “decision tree” shall be applied to the individual raw material to determine the level of the safety documents. Additional documents demonstrating that interaction between ingredients used in combination does not cause adverse effect shall be submitted (additional documents shall be based on evidence of historical use, safety and functionality, etc.). Provided toxicity study on compound ingredients was conducted, those additional documents on safety of interaction may be exempted.

※ In case of ingredients subjected to the Regulation on “Safety evaluation of Genetically Modified Organisms” (KFDA Notification), its safety shall be evaluated in accordance with this Regulation.

[Annexed the Form 1]

(Front)

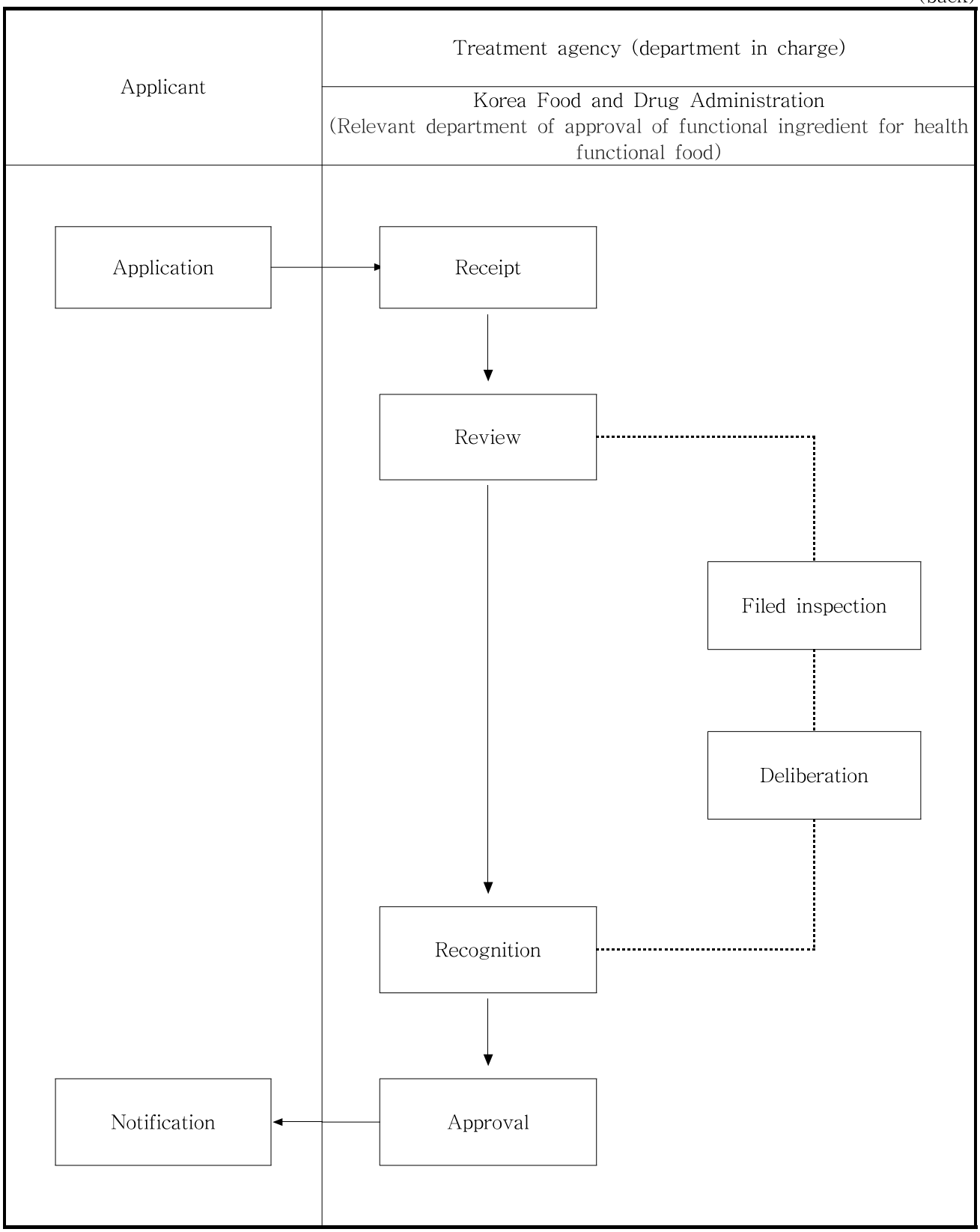
<table>
<tr><td colspan="6">Approval Application of Functional Ingredient for Health Functional Food</td><td>Treatment period</td></tr>
<tr><td colspan="6"></td><td>120 days</td></tr>
<tr><td rowspan="7">Applicant</td><td colspan="2">Representative</td><td colspan="4"></td></tr>
<tr><td colspan="2" rowspan="2">Name of business establishment</td><td rowspan="2"></td><td rowspan="2">Business permission/ report No.</td><td>Manufacture business</td><td></td></tr>
<tr><td>Import business</td><td></td></tr>
<tr><td colspan="2">Place of business</td><td colspan="4">(Tel) (Fax)</td></tr>
<tr><td rowspan="4">Imported health functional food</td><td>Receipt No.</td><td colspan="4"></td></tr>
<tr><td>Exporting country</td><td colspan="4"></td></tr>
<tr><td>Business establishment of manufacture</td><td colspan="4"></td></tr>
<tr><td>Location of business establishment</td><td colspan="4"></td></tr>
<tr><td colspan="3">Ingredient name</td><td colspan="4"></td></tr>
<tr><td colspan="7">Applying to approval of functional ingredient for health functional food under Article 5 of the Regulation on Approval of Functional Ingredient for Health Functional Food.

Date(YY/MM/DD):
Applicant (Signature)
To the Commissioner of the Food and Drug Administration</td></tr>
<tr><td colspan="6">※ Requisites of submission
1. Two copies of documents (Including an original copy)
2. A CD containing submitting documents
3. Product or test product and the standard of function component (or marker compound)
4. Written result of examination issued by a domestic health functional food examination laboratory</td><td>Fees
100,000 won</td></tr>
<tr><td colspan="7">※ Submission documents
1. Executive summary of whole submitted documents
2. Origin, developing history, approval and use status in domestic or foreign country etc.
3. Manufacturing methods and related documents for such establishment
4. Characteristics of the ingredients
5. Specification on functional component (or marker compound) and data on test method
6. Specification of detrimental substance and related data for test method;
7. Safety
8. Functionality contents and related documents for such establishment
9. Consumption amount, consumption method, warning notice for consumption and related documents for such establishment
10. Confirmation that ingredients are not identical with or similar to medicine</td></tr>
</table>

210㎜×297㎜(regular paper 60g/㎡(Recycle))

This application is processed as below.

(back)



[Annexed the Form 2]

(Front)

Domestic	Import

No:

Certificate of Functional Ingredient for Health Functional Food

Representative :

Name of business establishment :

Place of business :

Ingredient name :

Exporting country :

Name of business establishment in an exporting country :

Place of business establishment in an exporting country :

Approving this as functional ingredient for health functional food under Article 10 of the Regulation on Approval of Functional Ingredient for Health Functional Food.

Date(YY/MM/DD):

The Commissioner of Food and Drug Administration (Signature)

※ Attachment

1. Name of ingredient
2. Manufacturing standards (raw material, manufacturing methods, functional component (or maker compound), notice for manufacturing (specification of detrimental substance, etc.))
3. Requisites of product (functionality contents, daily consumption amount, notice for consumption, etc.)

210㎜×297㎜(Conservation paper 120g/㎡)

(back)

Modification contents		
Date (YY/MM/DD)	Contents	Name/Position of the person in charge(signature)

210㎜×297㎜(Conservation paper 120g/㎡)

[Attachment]

(Approval No.:)

Section		Approval contents
Name of ingredient		
Manufacturing standards	Raw material	
	Manufacturing methods	
	Functional component (or maker compound)	※ Including test methods
	Notice for manufacturing (specification of detrimental substance, etc.)	※ Including test methods
Requisites of product	Functionality contents	
	Daily consumption amount	
	Notice for consumption	
	Etc.	

[Annexed the Form 3]

<table>
<tr><td colspan="5">Application of Modification on Certificate of Functional Ingredient for Health Functional Food</td><td>Treatment period</td></tr>
<tr><td colspan="5"></td><td>5days</td></tr>
<tr><td rowspan="3">Applicant</td><td>Representative</td><td colspan="4"></td></tr>
<tr><td>Name of business establishment</td><td></td><td rowspan="2">Business permission/ report No.</td><td>Manufacture business</td><td></td></tr>
<tr><td>Place of business</td><td colspan="2">(Tel)</td><td>Import business</td><td></td></tr>
<tr><td>Ingredient name</td><td colspan="5"></td></tr>
<tr><td>Approval No.</td><td colspan="5"></td></tr>
<tr><td colspan="6">Contents of modification</td></tr>
<tr><td rowspan="2">Item of modification</td><td colspan="2">Contents of modification</td><td rowspan="2" colspan="3">Reasons for modification</td></tr>
<tr><td>before</td><td>after</td></tr>
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<tr><td colspan="6">Applying to modification of item mentioned in ‘Certificate of Functional Ingredient for Health Functional Food’ under Article 11 of the Regulation on Approval Functional Ingredient for Health Functional Food.

Date (YY/MM/DD):

Applicant (Signature)

To The Commissioner of Food and Drug Administration</td></tr>
<tr><td colspan="6">※ Requisites of submission
A copy of ‘Certificate of Functional Ingredient for Health Functional Food’</td></tr>
</table>

210㎜×297㎜(regular paper 60g/㎡(recycle))